

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

KANEKA CORPORATION,  
A Japanese Corporation.

Plaintiff,

v.

DESIGNS FOR HEALTH, INC.,  
A Delaware Corporation, and AMERICAN  
RIVER NUTRITION LLC, A Delaware  
Corporation

Defendants.

DEMAND FOR JURY TRIAL

C.A. No. \_\_\_\_\_

**COMPLAINT**

Plaintiff Kaneka Corporation (“Kaneka”) files this Complaint for Patent Infringement and Demand for Jury Trial against Designs For Health Inc. (“DFH”) and American River Nutrition LLC (“ARN”).

**NATURE OF THE ACTION**

1. This is an action for Patent infringement under the laws of the United States, Title 35, United States Code by Kaneka against DFH and ARN.

2. This action arises from DFH’s manufacture, use, offer for sale, and sale in the United States of the supplements, DuoQuinol and CoQnol (“Accused Products”) which, upon information and belief, were designed and developed by ARN, and manufactured, offered for sale and sold by DFH under the trademarks “DuoQuinol” and/or “CoQnol” These activities infringe, either literally or under the doctrine of equivalents, and induce others to infringe two Patents owned by Kaneka.

**THE PARTIES**

3. Kaneka is a Japanese Corporation with a head office at 1-12-32, Akasaka, Minato-Ku, Tokyo, Japan, and a head office at 2-3-18, Nakanoshima, Kita-Ku, Osaka, Japan.

4. DFH is a Delaware Corporation at 14 Commerce Blvd., Palm Coast, FL 32164. DFH may be served with process through its registered agent, Northwest Registered Agent Service Inc., 8 The Green, Ste. B, Dover, Delaware 19901.

5. ARN is a Delaware Corporation at 333 Venture Way, Hadley, MA 01035. ARN may be served through its registered agent, Northwest Registered Agent Service Inc., 8 The Green, Ste. B, Dover, Delaware, 19901.

**JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a).

7. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over the Defendants.

8. This Court has personal jurisdiction over DFH and ARN as both are Delaware Corporations.

9. This Court additionally has personal jurisdiction over the Defendants because upon information and belief, the Defendants have knowingly directly infringed, and induced infringement within this District by advertising, marketing and offering for sale the Accused Products within this District, to consumers, customers, distributors, resellers, partners and/or end users, and providing instructions, advertising, and/or marketing materials that facilitate, direct or encourage the use of the Accused Products.

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

## **BACKGROUND**

### **Kaneka's Innovations**

11. Kaneka Corporation is an international company that produces a number of different products at plants around the world. It has also been the world's premier supplier of Coenzyme Q<sub>10</sub> ("CoQ<sub>10</sub>") supplements for more than 40 years. CoQ<sub>10</sub> is found in every cell of the human body. The human body makes CoQ<sub>10</sub> and the cells use it to produce energy that the human body needs for cell growth and cell maintenance. It also protects the body from damage caused by harmful molecules. CoQ<sub>10</sub> levels in the body decrease with age, which explains why millions of people take Kaneka CoQ<sub>10</sub> on a daily basis. Kaneka sells CoQ<sub>10</sub> as a nutritional supplement, similar to vitamins.

12. There are two types of CoQ<sub>10</sub>. The oxidized form is known as Ubiquinone, and the reduced form is known as Ubiquinol. Kaneka was the first industrial scale manufacturer of Ubiquinone, starting in 1977. When exposed to air, reduced CoQ<sub>10</sub> (Ubiquinol) quickly undergoes a chemical reaction—oxidation—and converts to oxidized CoQ<sub>10</sub> (Ubiquinone). Kaneka was the first manufacturer in the world to succeed in the development of technology to stabilize Ubiquinol so that it did not quickly oxidize when exposed to air. Kaneka began sales of Ubiquinol in the U.S. in 2006. Kaneka has been awarded a number of patents covering its Ubiquinol products and due to that patent protection Kaneka is the only company that has the legal right to produce and sell Ubiquinol in the United States. DFH admits that the Accused Products are a form of Ubiquinol. (See Exhibit C)

13. During its 40 year history of producing CoQ<sub>10</sub> products, Kaneka has supported hundreds of CoQ<sub>10</sub> clinical research studies at universities and hospitals around the globe. Kaneka has focused its research support by working with top, independent academic research

institutions conducting research into the functionality and health benefits of all forms of CoQ<sub>10</sub> to ensure that the CoQ<sub>10</sub> products made by Kaneka are safe and effective. All CoQ<sub>10</sub> products made by Kaneka have satisfied all applicable FDA standards and other government agency requirements for safety and efficacy. Kaneka has ensured the safety and efficacy of its CoQ<sub>10</sub> products for the entire 40 year history of producing these products.

14. Over this 40 year period, Kaneka has been granted over 37 U.S. Patents covering the production of CoQ<sub>10</sub> products, and numerous CoQ<sub>10</sub> related Patents issued in other countries around the world.

#### The Asserted Patents

15. United States Patent No. 7,145,044 (the “’044 Patent”) titled “Method Of Producing Reduced Coenzyme Q<sub>10</sub> Using Solvent with High Oxidation-Protective Effect” was duly issued on December 5, 2006, and remains unexpired. A true and correct copy of the ’044 Patent is attached as Exhibit A and is assigned to and owned by Kaneka Corporation.

16. United States Patent No. 7,829,080 (the “’080 Patent”) titled “Stabilization Method Of Reduced Coenzyme Q<sub>10</sub>” was duly issued on November 9, 2010, and remains unexpired. A true and correct copy of the ’080 Patent is attached hereto as Exhibit B and is assigned to and owned by Kaneka Corporation.

#### The DFH Infringing Product and Activities

17. The Accused Products are DuoQuinol and CoQnol. DFH admits that DuoQuinol is a form of Ubiquinol, derived from Ubiquinone through a process involving the use of geranygeraniol (GG) and ascorbyl palmitate. (*See* Exhibit C.) Upon information and belief, the DuoQuinol product was designed and developed by Dr. Barrie Tan, the founder of ARN. ARN then provided DFH the information required to produce DuoQuinol on a commercial scale, and

the production was done by Ashley-Martin Manufacturing, the DFH manufacturing unit.<sup>1</sup> DFH markets, advertises, offers for sale, and sells the Accused Products under the name CoQnol.

18. Defendant ARN has induced the direct infringement of DFH by designing and developing the DuoQuinol product and providing DFH with the information required to produce DuoQuinol on a commercial scale. Upon information and belief, Ashley-Martin Manufacturing, the DFH manufacturing unit, does not have the experience to design and develop a new type of Ubiquinol like the DuoQuinol product. A review of the employees at Ashley-Martin Manufacturing on Linked In shows a number of employees with manufacturing and production experience, but none with a research background. In contrast, Dr. Tan has a PhD in Chemistry/Biochemistry, and the ARN website states that Dr. Tan's mission "is to deliver the highest quality nutritional products based on sound scientific research." Dr. Tan is also very familiar with Kaneka Corporation. In the 2015-2016 time period, Kaneka Corporation entered into business discussions with ARN. During those discussions Dr. Tan acknowledged that he knew Kaneka very well and followed the company closely. Dr. Tan also acknowledged that he had followed the science and chemistry of CoQ10 all of his life. ARN is also very familiar with the world of patents and patent litigation, as ARN has over 13 issued patents and pending patent applications, and ARN is currently the plaintiff in a patent infringement case in the Central District of California. Accordingly, upon information and belief, ARN had the expertise to design and develop a new form of Ubiquinol, and to provide that information to DFH. As Dr.

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<sup>1</sup> Upon information and belief, the manufacturing unit of DFH goes by the name of Ashley-Martin Manufacturing. Ashley-Martin Manufacturing LLC was initially formed in Delaware on November 6, 2006. On March 31, 2015, Ashley-Martin Manufacturing LLC merged with DFH, with DFH continuing as the surviving company.

Tan followed the science and chemistry of CoQ10 all of his life. ARN also had to know that Kaneka Corporation was the only company producing Ubiquinol. Also based on ARN's experience with patents and patent litigation, ARN had to know that Kaneka had a number of patents covering Ubiquinol. Therefore, when ARN provided information to DFH on how to produce DuoQuinol, it intentionally aided and encouraged DFH to directly infringe Kaneka Corporation's Ubiquinol patents, and thereby induced the direct infringement of DFH. Alternatively, if ARN did not take steps to investigate the patents held by Kaneka covering Ubiquinol products, it was unquestionably willfully blind in failing to conduct that investigation.

19. The Defendants have either induced infringement or infringed directly one or more claims of the Asserted Patents and continue to infringe (literally and under the doctrine of equivalents), directly, indirectly, and/or through agents or intermediaries by making, using, offering for sale and/or selling the Accused Product in the United States.

20. The DFH customers (including distributors and retailers) have infringed and/or continue to infringe (literally and under the doctrine of equivalents) directly, indirectly, and/or through agents or intermediaries, one or more claims of the Asserted Patents by using, offering for sale, and/or selling the Accused Product in the United States.

21. The DFH infringement has caused, is causing, and will continue to cause Kaneka to suffer damage, and Kaneka is entitled to recover damages in an amount proven at trial, but no less than a reasonable royalty as provided by 35 U.S.C. § 284.

**COUNT I**  
**(Direct Infringement of the '044 Patent by DFH)**

22. Kaneka incorporates each of the preceding paragraphs as if fully set forth herein.

23. DFH has been and is now directly infringing claims 1 and 13 of the '044 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling in the United States the Accused Products that infringe the claims of the '044 Patent.

24. By way of example, claim 13 of the '044 Patent reads as follows:

“13). A reduced coenzyme Q<sub>10</sub> crystal with a reduced coenzyme Q<sub>10</sub> /oxidized coenzyme Q<sub>10</sub> weight ratio of not lower 96/4”.

25. Exhibit D shows the tests done by Kaneka on the reduced Q<sub>10</sub> ratio in the CoQnol capsules produced and sold by DFH. Exhibit D includes three separate reports labeled Analysis Report 1, Analysis Report 2 and Analysis Report 3. Table 1 in Report 1 shows that the reduced Q<sub>10</sub> ratio was 99.7, more than the claimed requirement of not lower than 96/4. Reports 2 and 3 show that the reduced Q<sub>10</sub> found in the CoQnol capsule is crystalized. DFH thereby directly infringes claim 13 of the '044 Patent.

26. DFH's direct infringement of Claims 1 and 13 of the '044 Patent is further detailed in the claim charts attached as Exhibit E.

27. DFH has been, and is now, indirectly infringing the '044 Patent in violation of 35 U.S.C. § 271(b) by actively inducing the direct infringement of the '044 Patent by their distributors, retailers and customers, including at least by making, using, offering for sale and/or selling the Accused Products in the United States.

28. As a consequence of DFH's infringement of the '044 Patent, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty.

**COUNT II**  
**(Direct Infringement of the '080 Patent by DFH)**

29. Kaneka incorporates each of the preceding paragraphs as if fully set forth herein.

30. DFH has been, and is now, directly infringing claims 1, 5 and 15 of the '080 Patent, either literally or under the doctrine of equivalents, in violation of 35 U.S.C. § 271(a) by making, using, offering for sale, and/or selling in the United States the Accused Products that infringe the claims of the '080 Patent.

31. By way of example, claim 5 of the '080 Patent reads or follows;

“5) A reduced coenzyme Q10-containing composition, comprising reduced coenzyme Q10 and one or both of (a) and (b): (a) not less than 1.5 wt % to not more than 99 wt % of reduced coenzyme Q9 relative to reduced coenzyme Q10, and (b) reduced coenzyme Q11, wherein not less than 0.01 wt % of reduced coenzyme Q10 is contained in the composition, and wherein the proportion of reduced coenzyme Q10 relative to the total amount of coenzyme Q10 is not less than 90 wt %.”

32. DFH produces and sells DuoQuinol/CoQnol which is reduced coenzyme Q<sub>10</sub>. Exhibit D, Report 1, are Kaneka's test results on CoQnol capsules produced and sold by DFH. The tests show in Table 1 that the proportion of reduced coenzyme Q10, relative to the total amount of coenzyme Q10 was 99.7% and Table 2 shows that 88ug of Q11 was present in the CoQnol capsule. Accordingly, DFH directly infringes claim 5 of the '080 Patent. For the same reasons, DFH also directly infringes at least claims 1 and 15 of the '080 Patent.



33. DFH's infringement of Claims 1, 5, and 15 of the '080 Patent is further detailed in Exhibit E.

34. DFH has been, and is now, indirectly infringing the '080 Patent in violation of § 271(b) by actively inducing the direct infringement of the '080 Patent by their distributors, retailers and customers, including at least by making, using, offering for sale, and/or selling the Accused Products.

35. As a consequence of DFH's infringement of the '044 Patent, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty

**COUNT III**  
**(Induced Infringement by ARN of the '046 and '080 Patents)**

36. Kaneka incorporates each of the proceeding paragraphs as if fully set forth herein.

37. Upon information and belief, ARN has been, and currently is, inducing infringement of the '044 and '080 Patents in violation of 35 USC § 271(b) by knowingly encouraging and aiding DFH to make, use, sell or offer to sell the Accused Products in the United States which directly infringes the '044 and '080 Patents.

38. The Supreme Court in *Global-Tech Appliances Inc. v SEB S.A.*, 563 U.S. 754 (2011) held that induced infringement under 271(b) requires knowledge that the induced acts constitute patent infringement, but also held that the required knowledge could be shown under the doctrine of "willful blindness." The Supreme Court found two basic requirements to show "willful blindness:" (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. The Supreme Court specifically said that "[u]nder this formulation a willfully blind defendant is

one who takes deliberate actions to avoid conforming a high probability of wrongdoing and can almost be said to have actually known the critical facts.” The critical fact here is whether Dr. Tan believed there was a high probability that Kaneka had patents covering the production of Ubiquinol.

39. As set forth above, during the 2015-2016 business discussions Dr. Tan revealed that he was well aware of Kaneka and Kaneka’s products, including Ubiquinol and we quote; “I know of Kaneka, I know them very well and I follow the company closely.” “They provide high quality ingredients and they are a market leader.” “I am intrigued by Kaneka, I have been following the science and chemistry of CoQ10 all of my life and it is a passion of mine.” “I told Mr. (Kaneka employee name deleted) about my interests in CoQ10 and how I see CoQ10 and QH as good complementary products for (product name deleted).” *To be clear QH is another name for Ubiquinol.* Obviously Dr. Tan was very familiar with Kaneka, Kaneka’s CoQ10 products, including Ubiquinol, and certainly had to know that Kaneka was the only company with the right to sell Ubiquinol in the United States due to Kaneka’s patents covering Ubiquinol. Dr. Tan was also well aware of the value of patent protection as ARN is currently asserting an ARN patent in the Central District of California and ARN has been granted a number of U.S. patents. With this knowledge, ARN proceeded to aide and encourage DFH to produce the Ubiquinol Accused Products in the United States in a manner that ARN knew, or should have known, but for willful blindness, that the Ubiquinol Accused Products would infringe, or have a high probability of infringing one or more of Kaneka’s patents, which cover the production of Ubiquinol. Kaneka therefore alleges that ARN has been, and currently is, inducing the direct infringement of the ’044 and ’080 Patents by DFH.

40. As a consequence of ARN inducing infringement of the '044 and '080 Patents, Kaneka has suffered, is suffering, and will continue to suffer, damages in an amount not yet determined, but no less than a reasonable royalty

**PRAYER FOR RELIEF**

**WHEREFORE**, Kaneka requests the following relief:

- a) A judgment that DFH has directly infringed the '044 and '080 Patents;
- b) A judgment that ARN has induced direct infringement of the '044 and '080 Patents;
- c) Damages adequate to compensate for Defendants infringement but, in no event, less than a reasonable royalty on past and future infringing sales;
- d) An award of Kaneka's costs and expenses in this action,
- e) Entry of a preliminary and permanent injunction, pursuant to 35 U.S.C. § 283 enjoining each of the Defendants, and all of their respective agents, servants, officers, directors, employees, and all other persons acting in concert with them, directly or indirectly, from any further acts of infringement.

Such further and other relief as this Court may deem just and

**DEMAND FOR A JURY TRIAL**

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Kaneka demands a trial by jury on all issues triable as of right by a jury proper.

Date: February 16, 2021

**BAYARD, P.A.**

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